



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-1028; FRL-9360-6]

RIN 2070

Polyoxin D Zinc Salt; Amendment to an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing exemption from the requirement of a tolerance for residues of polyoxin D zinc salt when used as a fungicide on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes, and strawberries by expanding the current exemption to include all food commodities. This regulation establishes an exemption from the requirement of a tolerance for residues of polyoxin D zinc salt in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices. On behalf of Kaken Pharmaceutical Co., Ltd., Conn & Smith, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting that EPA amend the existing exemption from the requirement of a tolerance for polyoxin D zinc salt. This regulation eliminates the need to establish a maximum permissible level for residues of polyoxin D zinc salt under the FFDCA.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with

the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-1028, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Colin G. Walsh, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0298; email address: walsh.colin@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-1028 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-1028, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL-9335-9), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F7940) by Conn & Smith, Inc., Agent, 6713 Catskill Road, Lorton, VA 22079, on behalf of Kaken Pharmaceutical Co., Ltd. The petition requested that 40 CFR 180.1285 be amended by expanding the current

exemption to include all food commodities, thus establishing an exemption from the requirement of a tolerance for residues of polyoxin D zinc salt in or on all food commodities. This notice referenced a summary of the petition prepared by the petitioner Conn & Smith, Inc., on behalf of Kaken Pharmaceutical Co., Ltd., which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider “available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

EPA established a tolerance exemption for polyoxin D zinc salt in a final rule published in the **Federal Register** on November 19, 2008, (73 FR 69559) (FRL-8389-5), which supported the uses as a fungicide on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes, and strawberries. The toxicological data submitted to support the previous tolerance exemption included the following: Acute (six-pack) toxicity, mutagenicity, subchronic (90-day oral), developmental, and chronic/oncogenicity studies. All of the studies/information submitted to support the previous tolerance exemption indicated a lack of toxicity hazards for mammals, and EPA concluded that there is a reasonable certainty of no harm to humans, including infants and children, from the proposed food uses of polyoxin D zinc salt. This amendment proposes to expand the tolerance exemption to include all food commodities when applied as a fungicide and used in accordance with good agricultural practices. In support of this expansion of the tolerance exemption, new data have been

generated by the petitioner and reviewed by EPA to further address the developmental toxicity (OCSPP Guideline No. 870.3700) and mutagenicity (OCSPP Guideline Nos. 870.5100 and 870.5375) data requirements. The data are required when the use of the substance under widespread and commonly recognized practices may reasonably be expected to result in significant exposure to humans, specifically females of child-bearing age for the developmental toxicity data requirement. The rest of the toxicological profile as stated in the **Federal Register** of November 19, 2008, and referenced herein, has not changed. A copy of the November 19, 2008 final rule document (73 FR 69559) is located under docket ID number EPA-HQ-OPP-2008-0417. A copy of the risk assessment cited herein (See Ref.) is located under docket ID number EPA-HQ-OPP-2011-1028.

As discussed in the **Federal Register** of November 19, 2008 polyoxin D zinc salt is a brown musty smelling powder derived through the fermentation of the microbe *Streptomyces cacaoi* var. *asoensis*, which was isolated from a soil sample collected from Japan. This biochemical active ingredient has a non-toxic mode of action, which acts against fungi by inhibiting chitin growth in the cell walls, thus precluding the development of fungal colonies. Its effects are considered fungi-exclusive in that it has no mode of action relative to mammals and passes through mammalian digestive systems. Polyoxin D zinc salt does not persist in the environment and has a well understood low toxicity profile.

As stated previously in this Unit (III), new toxicity data have been submitted in support of the request by the petitioner to expand the current tolerance exemption to cover all food commodities. These data include:

1. A prenatal developmental toxicity study; and

2. Two mutagenicity studies.

All new data, coupled with the data submitted to support the previous tolerance exemption (73 FR 69561), confirm a lack of human health hazard, as noted and reported in the original assessment of the tolerance exemption, associated with dietary exposures of polyoxin D zinc salt and fully demonstrate the lack of acute, subchronic, and chronic toxicity. Summaries of the new toxicological data submitted in support of the expansion of the tolerance exemption follow.

A. Mutagenicity

Two new mutagenicity studies were performed for polyoxin D zinc salt to support the expansion of the tolerance exemption. The mutagenicity studies as described herein, along with the mutagenicity studies submitted to support the previous tolerance exemption (73 FR 69561), confirm that polyoxin D zinc salt is not a mutagen and that consumption of food commodities that have been treated with this substance when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

1. A reverse gene mutation assay in bacteria Master Record Identification Number ((MRID) 48653313) using the technical grade of polyoxin D zinc salt, dissolved in dimethyl sulfoxide (DMSO), with and without metabolic S9 activation, showed no mutagenic effects or evidence of cytotoxicity or insolubility even at the limiting dose of 5,000 ug/plate (See Ref.). Therefore, polyoxin D zinc salt is considered to be non-mutagenic under the conditions of this assay.

2. An *in vitro* mammalian chromosome aberration test (MRID 48653314) using the technical grade of polyoxin D zinc salt, dissolved in DMSO, with and without

metabolic S9 activation, showed clastogenic potential in Chinese hamster lung cells (CHL/IU) with and without activation (See Ref.). In Experiment I, polyoxin D zinc salt was tested up to dose levels that caused >50% cell lethality without activation (260 µg/mL) and with activation (1,600 µg/mL). Without activation, the frequencies of the metaphases with structural chromosome aberrations (excluding gaps) were 14.5% and 7.5% at test article concentrations of 186 and 260 µg/mL, respectively. With activation, the frequency of metaphase cells with structural chromosome aberrations (excluding gaps) was 9.5% at a test article concentration of 1,600 µg/mL. The frequency of polyploid metaphase cells showed no increases either without or with activation. In Experiment II, a 24-hour continuous treatment without activation resulted in a 8.0% frequency of metaphases with structural chromosome aberrations (excluding gaps) at the concentration of 133 µg/mL. There were no increases in the frequency of polyploid metaphases.

Although the submitted *in vitro* mammalian chromosome aberration test showed clastogenic potential, the results were not reproducible at the dose levels reported in the experiment. In addition, the mutagenicity data submitted to support the previous tolerance exemption (73 FR 69562), which included three complimentary Tier I mutagenicity tests and a Tier II mammalian erythrocyte micronucleus *in vivo* test, showed no mutagenic effects, including no clastogenic potential (no chromosomal aberrations). Furthermore, the lack of systemic toxicity noted in the following developmental toxicity section (Unit III.B) and the fact that no effects were reported in the Tier III 2-generation reproduction study submitted for the previous tolerance exemption (73 FR 69562), indicate that polyoxin D zinc salt is not mutagenic or

clastogenic. Therefore, based on the weight of evidence of the mutagenicity data submitted to support this expansion of the tolerance exemption and the previous tolerance exemption (73 FR 69561), the mutagenicity data and information are sufficient to confirm that polyoxin D zinc salt is not a mutagen, and that consumption of food commodities that have been treated with this substance when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

B. Developmental Toxicity

A new developmental study (MRID 48653315) was performed for polyoxin D zinc salt to support the expansion of the tolerance exemption. No treatment-related effects were observed in general appearance, body weight, adjusted for gravid uterine weight, weight gain, or food consumption in maternal rats at the doses tested (0, 100, 300, and 1,000 milligrams/kilograms bodyweight/day (mg/kg bw/day) (See Ref.). Necropsy observations showed that almost all rats (20/24) in the 1,000 mg/kg/day group highest dose tested (HDT) had thickening of the limiting ridge. Therefore, the lowest observed adverse effect level (LOAEL) for maternal toxicity of polyoxin D zinc salt in rats is 1,000 mg/kg bw/day based on gross lesions in the stomach (thickening of the limiting ridge). The no observed adverse effect level (NOAEL) for maternal toxicity is 300 mg/kg bw/day based on no effects observed at this dose. Although an effect of gross lesions in the stomach was found in maternal rats at the limit dose tested (1,000 mg/kg bw/day), there were no reported systemic effects in maternal rats at this dose. The effect in the stomach lining was limited to a localized gastric irritation due to the route of entry (oral gavage) at the limit dose tested (1,000 mg/kg bw/day), which is typical of the nature of the test substance.

For developmental toxicity, no treatment-related effects were observed on developmental parameters including gravid uterine weight, placental weight, mean numbers of corpora lutea and implantation sites, numbers of early and later resorptions (dead or resorbed embryos or fetuses), number of live fetuses per dam, implantation index, viability index, sex ratio, and male and female body weight. The incidence of external, visceral, and skeletal variations and anomalies were not affected by treatment of polyoxin D zinc salt. Based on no effects observed for developmental toxicity at any doses tested, the NOAEL for developmental toxicity is greater than 1,000 mg/kg bw/day HDT. The LOAEL was not identified for developmental toxicity, suggesting that the test animals could have tolerated a higher dose.

Based on the developmental toxicity data submitted for this expansion to the tolerance exemption, and the Tier III 2-generation reproduction study submitted for the previous tolerance exemption (73 FR 69562), which showed no reproductive effects at the limit dose tested, there are sufficient data and information to confirm that polyoxin D zinc salt is not a developmental toxicant, and that consumption of food commodities that have been treated with this substance when used as a pesticide is safe and will not result in any harm to human health from dietary exposure.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary risks to humans are considered negligible based on the lack of dietary toxicological endpoints for polyoxin D zinc salt and its non-toxic mode of action as a fungi-specific chitin synthetase inhibitor that passes through mammalian digestive systems. No significant acute, subchronic, mutagenic, immunotoxic, developmental, or chronic dietary toxicity hazards were identified in the studies submitted to support this expansion of the tolerance exemption or the previous tolerance exemption (73 FR 69562). Based on polyoxin D zinc salt's lack of dietary toxicity hazards for mammals, no aggregate dietary exposure concerns are expected.

1. *Food.* The petitioner submitted three nature of residue studies (MRIDs 486533-09 through -11) in plants (grapes, tomatoes, and lettuce) to support this expansion of the tolerance exemption. The three nature of residue studies represent EPA Crop Groups 13 (grapes), 08 (tomatoes), and 04 (lettuce). The total radioactive residue (TRR) levels measured were 0.520 parts per million (ppm) at day 1; 0.538 ppm at day 14; and 0.495 ppm at day 30 after the final application for the grape plant (See Ref.). For tomato plants, 0.073 ppm of polyoxin D was found 14 days after the last treatment on the tomato fruit. For lettuce, 0.025 ppm at day 7 and 0.107 ppm at day 14 were detected in the head of lettuce after final application.

In addition, a terrestrial exposure model (T-Rex) was performed for the previous tolerance exemption (73 FR 69562), which indicated that it is highly unlikely that there will be adverse effects resulting from the use of polyoxin D zinc salt via the oral route of exposure. EPA's T-Rex calculations delimit aggregate dietary consumption of residues to no more than 40 ppm, a level that is far below the HDT in any of the toxicity testing.

Based on the residue data submitted for this expansion of the tolerance exemption, and the T-Rex residue modeling data from the previous tolerance exemption (73 FR 69562), any residues found are far below any toxicological endpoints identified in this expansion of the tolerance exemption (developmental toxicity NOAEL greater than 1,000 mg/kg bw/day; maternal toxicity NOAEL of 300 mg/kg/day) or in the previous tolerance exemption (73 FR 69561). The previous tolerance exemption showed an acute oral toxicity median lethal dose (LD₅₀) greater than 10,000 mg/kg; a subchronic oral toxicity NOAEL of greater than 1,333 mg/kg/day and 119 mg/kg/day in female and male rats, respectively; a subchronic oral toxicity LOAEL of 1,166 mg/kg/day in male rats based on decreased body weight gain, food consumption, and food efficiency; and a chronic oral toxicity NOAEL 2,058.7 mg/kg bw/day in male rats and 2,469.8 mg/kg bw/day in female rats.

In summary, the residue and toxicity data demonstrate a lack of aggregate dietary risk that is sufficient to support this expansion of the tolerance exemption.

2. *Drinking water exposure.* As stated in the previous tolerance exemption (73 FR 69562), there is a small potential for trace amounts of polyoxin D zinc salt to enter drinking water sources after a significant rainfall, via surface water runoff, and/or via incidental spray drift. The petitioner submitted a photodegradation in water study (MRID 48653305) to support this tolerance exemption. The results of the study show that polyoxin D zinc salt has a net photolytic half-life of 0.4 days in sterile natural water (See Ref.) . Even if residues of polyoxin D zinc salt enter water sources, residues are expected to degrade and be so diluted as to be negligible. The data and information demonstrate a

lack of aggregate dietary risk via drinking water and is sufficient to support this expansion of the tolerance exemption.

B. Other Non-Occupational Exposure

No new non-occupational exposure is expected to result from the new food uses of polyoxin D zinc salt. No health risks are expected from any non-occupational exposure to polyoxin D zinc salt based on the data submitted for the previous tolerance exemption (73 FR 69562) and for this expansion of the tolerance exemption.

1. *Dermal exposure.* No new non-occupational dermal exposures are expected to result from the new food uses of polyoxin D zinc salt resulting from this expansion of the tolerance exemption. Any new dermal exposure associated with this expansion of the tolerance exemption is expected to be occupational in nature.

2. *Inhalation exposure.* No new non-occupational inhalation exposures are expected to result from the new food uses of polyoxin D zinc salt resulting from this expansion of the tolerance exemption. Any new inhalation exposure associated with this expansion of the tolerance exemption is expected to be occupational in nature.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information concerning the cumulative effects of a particular pesticide’s residues and other substances that have a common mechanism of toxicity.”

EPA has not found polyoxin D zinc salt to share a common mechanism of toxicity with any other substances, and polyoxin D zinc salt does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action,

therefore, EPA has assumed that polyoxin D zinc salt does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure safety, which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Relevant data and information submitted for the previous tolerance exemption (73 FR 69560) and for this expansion of the tolerance exemption indicate that polyoxin D zinc salt has negligible acute, subchronic, chronic, and developmental toxicity. Moreover, polyoxin D zinc salt is defined by its fungistatic non-toxic mode of action, and demonstrates no significant mammalian effect. Therefore, the Agency concludes that

there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of polyoxin D zinc salt. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on polyoxin D zinc salt do not demonstrate toxic potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated above, and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for polyoxin D zinc salt.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of polyoxin D zinc salt. Therefore, the existing exemption from the requirement of a tolerance for residues of polyoxin D zinc salt when used as a fungicide on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes, and strawberries is amended by establishing an exemption from the requirement of a tolerance for residues of polyoxin D zinc salt in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices.

IX. References

The reference used in this document is in the OPP docket listed under docket ID EPA-HQ-OPP-2011-1028 and may be seen by accessing the www.regulations.gov website. A copy of the previous final rule published in the **Federal Register** on November 19, 2008, is in the OPP docket listed under docket ID EPA-HQ-OPP-2008-0417.

U.S. EPA. 2011. Memorandum from Manying Xue to Colin Walsh. Polyoxin D zinc salt (EPA Reg. #: 68173-1), Containing 23.8% of Polyoxin D Zinc Salt (Active Ingredient). Science Review of Product Chemistry, Residue Chemistry, Non-Target Organism and Toxicity Data in Support of label Amendment. U.S. Environmental Protection Agency Office of Pesticide Programs. May 11, 2012.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on

the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 29, 2012.

Keith A. Matthews,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1285 is revised to read as follows:

180.1285 Polyoxin D zinc salt; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of polyoxin D zinc salt in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices.

[FR Doc. 2012-22315 Filed 09/11/2012 at 8:45 am; Publication Date: 09/12/2012]